

## § 414.400

either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies.

(b) Payment is made in accordance with the rules set forth in § 413.170 of this chapter.

[56 FR 43710, Sept. 4, 1991]

EFFECTIVE DATE NOTE: At 75 FR 49202, Aug. 12, 2010, § 414.335 was revised, effective January 1, 2011. For the convenience of the user, the revised text is set forth as follows:

### § 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in § 413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230

## Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

### § 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

[72 FR 18084, Apr. 10, 2007]

### § 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

*Bid* means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

*Competitive bidding area (CBA)* means an area established by the Secretary under this subpart.

*Competitive bidding program* means a program established under this subpart within a designated CBA.

*Composite bid* means the sum of a supplier's weighted bids for all items within a product category for purposes of

## 42 CFR Ch. IV (10–1–10 Edition)

allowing a comparison across bidding suppliers.

*Contract supplier* means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

*Covered document* means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards.

*Covered document review date* means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

*DMEPOS* stands for durable medical equipment, prosthetics, orthotics, and supplies.

*Grandfathered item* means all rented items within a product category for which payment was made prior to the implementation of a competitive bidding program to a grandfathered supplier that chooses to continue to furnish the items in accordance with § 414.408(j) of this subpart and that fall within the following payment categories for competitive bidding:

(1) An inexpensive or routinely purchased item described in § 414.220 of this part.

(2) An item requiring frequent and substantial servicing, as described in § 414.222 of this part.

(3) Oxygen and oxygen equipment described in § 414.226 of this part.

(4) Other DME described in § 414.229 of this part.

*Grandfathered supplier* means a non-contract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

*Hospital* has the same meaning as in section 1861(e) of the Act.

*Item* means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the

beneficiary. Items that may be included in a competitive bidding program are:

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

*Item weight* is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

*Mail order contract supplier* is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

*Metropolitan Statistical Area (MSA)* has the same meaning as that given by the Office of Management and Budget.

*Minimal self-adjustment* means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

*Nationwide competitive bidding area* means a CBA that includes the United

States, its Territories, and the District of Columbia.

*Nationwide mail order contract supplier* means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.

*Network* means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire CBA.

*Noncontract supplier* means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

*Physician* has the same meaning as in section 1861(r) of the Act.

*Pivotal bid* means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

*Product category* means a grouping of related items that are used to treat a similar medical condition.

*Regional competitive bidding area* means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

*Regional mail order contract supplier* means a mail order contract supplier that furnishes items in a regional competitive bidding area.

*Single payment amount* means the allowed payment for an item furnished under a competitive bidding program.

*Small supplier* means, a supplier that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

*Supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

*Treating practitioner* means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

*Weighted bid* means the item weight multiplied by the bid price submitted for that item.

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009]

#### § 414.404 Scope and applicability.

(a) *Applicability.* Except as specified in paragraph (b) of this section, this